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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,848	08/22/2000	Maria Pilar Prieto-Dapena	1379-1-013	2038

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EXAMINER	
GUZO, DAVID	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/600,848	PRIETO-DAPENA ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Detailed Action

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Applicant is also reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. **In the instant case applicant uses legal phraseology such as "Said studies show..." in the Abstract.** The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure

concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 and 10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Applicants claim a nucleotide sequence "constituted by" the Ha ds10 G1 gene wherein the sequence can be SEQ ID NO:1 or sequences homologous to it. Applicants also claim a nucleotide sequence "including" Ha ds10 G1 gene coding and 3' flanking sequences. Because these nucleotide sequences are not claimed as isolated or recombinant and because applicants use open claim language ("constituted by" or" including") to claim the sequences, the sequences read on products of nature.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international

application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language.

Claims 1 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Hanecak et al.

Applicants claim fragments of SEQ ID NO:1 or sequences at least 70% homologous to SEQ ID NO:1. Applicants also claim a "part" of a nucleotide sequence constituted by constructions ds10F1, ds10F2, ds102Δ, ds10F3 and ds10EC1. The fragments or parts are not limited by size or function.

Hanecak et al. (U.S. Patent 5,952,490, issued 9/14/92, filed 6/12/95, see whole document, particularly Tables 1 and 3) recite fragments of the instantly claimed SEQ ID NO:1 or the recited constructions comprising portions of SEQ ID NO:1. For example, Hanecak et al. recite oligonucleotide sequences such as TTGGGG and TTGGGGTT, etc. which are nucleotides 235-240 and 235-242, respectively, of instantly recited SEQ ID NO:1 and GGGG which is present at numerous locations in SEQ ID NO:1 (for example, at positions 923-926, 1034-1037, 2260-2263, 2807-2810, etc.) and in the recited constructions. Hanecak et al. therefore teaches the claimed invention.

Claim 24 is rejected under 35 U.S.C. 102(e) as being anticipated by Radin et al.

Applicant claims substances obtained from the use of transgenic plants to express a

protein of interest wherein said protein is encoded by a chimeric gene comprising regulatory elements of the Ha ds10 G1 gene operably linked to the coding sequence of the protein.

Radin et al. (U.S. Patent 5,929,304, see whole document, particularly the Abstract and Claim 59) recites the production of a protein of interest (a lysosomal enzyme) from a transgenic plant (which can be tobacco). It is noted that applicant appears to be claiming the product in a product-by-process context. In this context, it is the patentably of the product that is at question, not the process by which it is produced. If a prior art product is identical or obvious to the claimed product but is produced by a different method, the product can be rejected under 35 USC 102 or 103 (See MPEP 2113). In the instant case, the claimed substances produced by the instant method are (absent evidence to the contrary) identical to those produced by the prior art exemplified by Radin et al. because the use of one promoter to drive expression of a gene product in a given cell does not (absent evidence to the contrary) impart properties to said gene product which would distinguish it from the same gene product expressed in the cell by a different promoter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Almoguera et al.

Applicants' invention is as recited in the above 35 USC 102(e) rejection.

Almoguera et al. (Plant Mol. Biol., 1992, Vol. 19, pp. 781-792, see whole article, particularly Fig. 1A) recites a portion of the Ha ds10 G1 gene as represented by SEQ ID NO:1 (5' flanking sequences, an exon and sequences of an intron). Almoguera et al. therefore recites a fragment of SEQ ID NO:1 and a part of the constructs recited in claim 9.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants appear to claim a genus of Ha ds10 G1 genes wherein said genes have sequence homology to SEQ ID NO:1 by at least 70% but less than 95% or at least 80%. Applicant discloses the Ha ds10 G1 gene from the sunflower. Applicant indicates that this gene belongs to the Class I LEA gene family. Applicants also claim a vector containing the gene, host cells and transgenic plants containing the vector and methods of making proteins comprising use of the claimed Ha ds10 G1 sequences.

The written description requirement for a claimed genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or art recognized correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicant was in possession of the claimed genus.

In the instant case, applicant claims Ha ds10 G1 genes which have certain sequence homologies to the single gene sequence determined by applicant. However, neither the prior art nor applicant discloses a relationship between the structure of the sunflower Ha ds10 G1 gene and it's function. Indeed, applicant indicates that the "distribution and accumulation pattern of Ha ds10 G1 is different from that presented by other plant genes belonging to the same family..." (Page 12 of the specification) and therefore comparisons between the Ha ds10 G1

gene and other members of the family to which it belongs may not be fruitful with regard to defining functional motifs. Applicants provide no relationship between the structure of the Ha ds10 G1 gene and the functional behavior of the protein encoded by said gene. Also, the regulatory elements of genes (promoter regions, 3' regulatory sequences, etc.) cannot be predicted based upon the sequence of one example. These elements must be determined empirically. The disclosure of one example of a Ha ds10 G1 gene cannot therefore be considered to constitute a representative number of examples sufficient to indicate to the skilled artisan that applicants were in possession of the claimed genus. Also, given the lack of a disclosed or art recognized relationship between the structure of the Ha ds10 G1 gene and it's functions in the cell, it must be considered that the skilled artisan would not conclude that applicant was in possession of the claimed genus. Given that applicants were not in possession of the claimed genus of sequences, applicants were also not in possession of the cells and transgenic plants containing said sequences and the methods of use of said sequences to express proteins.

It is noted that the claims can also be read as reciting nucleotide sequences homologous to SEQ ID NO:1 and not having the functional activity of the Ha ds10 G1 gene (SEQ ID NO:1). If this interpretation is given to the claims, the following scope of enablement rejection is warranted.

Claims 1-9 and 12-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleotide sequences at least 70% homologous to or less than 95% homologous to SEQ ID NO:1 and possessing the activity of the Ha ds10 G1 gene, vectors, host cells and transgenic plants containing said sequences and methods of use of said sequences to express proteins, does not reasonably provide enablement for sequences homologous to SEQ ID NO:1 and not possessing the activity of the Ha ds10 G1 gene and use of said sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants, as can best be determined, appear to claim sequences which are homologous to SEQ ID NO:1 but do not have the functional activity of SEQ ID NO:1. With regard to the various constructions of claims 9 and 13, it can be interpreted that these constructs can be in a nucleotide sequence in addition to the sequences homologous to SEQ ID NO:1 and hence are irrelevant to the issue at hand.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures coupled with information known in the art without undue experimentation (See *United States v. Telectronics Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988).

Whether undue experimentation is required is not based upon a single factor, but rather is a conclusion reached by weighing many factors (See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). These factors include the following:

1) Unpredictability of the art. The art with regard to use of nucleotide sequences which do not have a known function is inherently unpredictable. The function of each sequence would need to be empirically determined.

2) State of the art. The state of the art with regard to determining whether a particular nucleotide sequence has some activity or encodes a useful protein is developed. However, the art here would involve trial and error experimentation to determine whether a given nucleotide sequence had some activity or encodes a polypeptide with some function.

3) Amount of guidance provided by applicants. Applicants provide no guidance on how the skilled artisan would use nucleotide sequences which are within the recited degree of homology to SEQ ID NO:1 but do not possess the activity of a Ha ds10 G1 gene.

4) Scope of the claims. The claims are very broad and read on millions of different nucleotide sequences with undisclosed function.

5) Number of working examples. Applicants present no working examples of nucleotide sequences which are within the recited degrees of homology to SEQ ID NO:1 and have a recited

function.

6) Nature of the invention. The invention involves the empirical determination of function for nucleotide sequences.

7) Level of skill in the art. The level of skill in the art is high; however, the skilled artisan would need to practice trial and error experimentation in order to ascertain the function (if any) of nucleotide sequences which have no disclosed function.

Given the analysis of the factors which the courts have determined are critical in determining whether a claimed invention is enabled, it must be concluded that the skilled artisan would have needed to have conducted undue and excessive trial and error experimentation in order to practice the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (and dependent claims) are vague in the recitation of the phrase "nucleotide sequence constituted by" because it is unclear whether the phrase "constituted by" is open or

closed claim language. Applicants are encouraged to use legally recognized transitional phrases such as "comprising" or "consisting of", etc. in drafting the claims. In the absence of a definition by applicants, the term "constituted by" will be interpreted here as open language.

Claim 1 is also vague in that applicants claim a nucleotide sequence constituted by the "Ha ds10 G1 gene, its promoter, Ha ds10 G1 5'- and 3' flanking sequences". Since a "gene" is generally recognized to include the coding region, introns, promoter and associated sequences involved in expression, etc., applicants claim language reciting the Ha ds10 G1 gene and then several of the genes' constituent parts is confusing and appears to be redundant.

Claim 1 is vague in that it is unclear if the sequences recited as being at least 70% homologous to SEQ ID NO:1 or its' complement encode a Ha ds10 G1 gene or merely include all sequences (independent of function) with the recited percent homology to SEQ ID NO:1 or its' complement.

Claim 1 is vague in that applicants claim nucleotide sequences identical to SEQ ID NO:1. Since only one sequence can be "identical" to SEQ ID NO:1 it is unclear what other sequences are being claimed. Is applicant claiming sequences identical to portions of SEQ ID NO:1?

Claim 1 is vague in the recitation of the phrase "...sequences being homologous being at least 70% homologous..." because this language is confusing and redundant.

Claim 6 is vague in that the relationship between the "chimeric gene" and the Ha ds10 G1

gene is unclear, are they operably linked in some fashion or does the chimeric gene comprise portions of the Ha ds10 G1 gene sequence?

Claim 7 is vague in that the metes and bounds of the claimed subject matter are unclear. It is unclear what sequences are "suitable" for expression of a chimeric gene. Are these "suitable" sequences from the Ha ds10 G1 gene or from some other sources?

Claim 8 is vague in the recitation of the phrase "...is specifical of seeds...". The examiner is not familiar with the term "specifical".

Claim 9 is vague in that the metes and bounds of the claimed subject matter are unclear. Applicants recite a nucleotide sequence "constituted by" several expression constructs (i.e ds10F1, ds10F2, etc.) and a plasmid (ds10EC1). It is unclear if applicants mean to claim a sequence which possesses all of these constructs and plasmids or if applicants mean to recite them in the alternative.

Claim 10 is vague because it depends from itself.

Claim 11 is vague in that applicants recite a nucleotide sequence "including ds10F2 and ds10F2Δ **in constructions** (emphasis added)." It is unclear what applicants mean by the phrase "in constructions", are these "constructions" inside or outside the recited nucleotide sequence?

Claim 13 is vague in that applicants recite a nucleotide sequence "...contained in **constructions** (emphasis added) ds10F3." Since ds10F3 is a single construction, it is unclear

what multiple "constructions" applicants are referring to.

Claim 14 is vague in that the relationship between the nucleotide sequence of claim 1 and the chimeric gene is unclear, are they operably linked in some fashion?

Claims 17-19, 22 and 23 provide for the use of nucleotide sequences or transgenic plants, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 17-19, 22 and 23 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 3 and 5 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 3 and 5 recite nucleotide sequences homologous **by less than 95% to SEQ ID NO:1**; however, these claims depend from claim 1

which recites sequences limited to being **at least 70% homologous to SEQ ID NO:1**. Since a sequence less than 95% homologous to SEQ ID NO:1 can include sequences which are less than 70% homologous to SEQ ID NO:1, claims 3 and 5 do not further limit the subject matter of the claim from which they depend.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be sent directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
December 30, 2002

DAVID GUZO
PRIMARY EXAMINER